

NOV 18 2004

EXHIBIT 2
510(k) Summary

SEDECAL SA Pelaya 9- Poligono Industrial Rio De Janeiro 28110 -Algete Madrid Spain Tel (34) 91-628 0544/91-628 1592 Fax (34) 91-628 0574 (Foreign Manufacturer)	SEDECAL USA, Inc. 2910 N. Arlington Heights Rd. Arlington Heights Illinois 60006 Tel 847-394-6960 Fax 847-394-6966 (Initial Importer) Contact: Devan Moser
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October 22, 2004

- 1. Identification of the Device:**
 Proprietary-Trade Name: Sedecal Mobile Radiographic Systems with Digital Detector
 Classification Name: Mobile X-ray system,
 Product Codes Product Code 90 IZL and MQB
 Common/Usual Name: General purpose mobile diagnostic X-ray Unit.
- 2. Equivalent legally marketed devices:** Sedecal Mobile X-Ray Units K012663 and Canon CXDI-50G Digital Radiography, K031447. The MODIFIED device COMBINES these two units.
- 3. Indications for Use (intended use)** The Sedecal Mobile Radiographic Systems with Digital Detector are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.
- 4. Description of the Device:** Sedecal Mobile X-ray Units with Digital Detector are mobile units which operate from 120 or 220 V 50-60~ AC or batteries. The units utilize high frequency inverters. The usual safety precautions regarding the use of x-rays must be observed by the operator. This modified device combines two FDA cleared devices by way of a common user interface, a color LCD touch panel. The X-Ray generator is controlled by a serial port on the CANON CXDI-50G.
- 5. Safety and Effectiveness, comparison to predicate device.** The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart, The Sedecal Portable X-ray Units with Detector

Characteristic	Model Mobile K012663 (Two models)	Canon CXDI-50G Digital Radiography, K031447	Sedecal Mobile X-ray Units with Detector (Combination device)
Intended Use:	Mobile general purpose diagnostic X-ray unit	SAME	SAME
Size		Imaging Area 14 x 17	SAME (Combined device) (A stand has been added)
Weight (battery version)	1045 lb	10.6 lb	964 lb.
Energy Source:	90 to 285 VAC (50-60 Hz) or Batteries	100V, 120V, 230/240V(50/60Hz)	SAME (Combined device)
User Interface	Up-Down pushbuttons for kVp and mAs. KVp adjustable in 1 kVp steps	Software Driven Touch Panel LCD	Software Driven Touch Panel LCD (Combined device)
Power	20 or 30 kW	N/A	Models up to 50 kW
Exposure times	0.001 - 8 SECONDS $\pm(1\%+0.1 \text{ MS})$	N/A	SAME (Combined device)
Ma.	10, 12.5, 16, 20, 25, 32, 40, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 50, 64, 80, 100, 125, 160, 200, 250, 320 200, (400, and 500 on 30 kw unit) $\pm(5\%+0.1 \text{ MA})$	N/A	SAME (Combined device)
kVp	40 to 150 in 1 kVp steps (30 kw unit)	N/A	SAME (Combined device)
Resolution	N/A	160 x 160 microns pixel pitch, with approximately 6 million pixels and 4,096 gray scale contrast	SAME (Combined device)
Method of Control	Dedicated Touch Panel	Software Driven Touch Panel LCD	SAME as CANON. Or original Dedicated Touch Panel
Performance Standard	21 CFR 1020.30	SAME	SAME
Electrical safety:	IEC 60601-1	SAME	SAME

7. Conclusion

After analyzing bench, user, and standards testing data, it is the conclusion of Sedecal that the Sedecal Mobile X-ray Units with Digital Detector are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEDECAL SA
% Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

AUG 23 2013

Re: K043002
Trade/Device Name: Sedecal Mobile X-Ray Units with Digital Detector
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL and MQB
Dated: October 27, 2004
Received: November 1, 2004

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of November 18, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

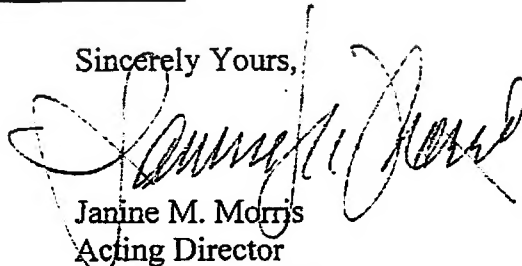
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043002

Device Name: Sedecal Mobile X-Ray Units with Digital Detector

Indications For Use:

The Sedecal Mobile Radiographic Systems with Digital Detector are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

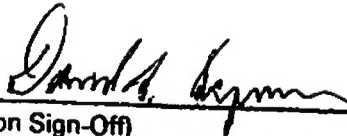
Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K043002

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